Ex. 1

Meghan Handy, Individually and as Surviving Child and Personal Representative of the Estate of Brenda Lee Rozek, Deceased
8 Rollins Road
North East, Maryland 21901

and

Neil E. Rozek
761 Ragan Road
Conowingo, Maryland 21918

and

Kristen Lowery
761 Ragan Road
Conowingo, Maryland 21918

and

Frank D. Ragan, Sr.
440 Johnson Road
Conowingo, Maryland 21918

and

JoAnne Ragan
440 Johnson Road
Conowingo, Maryland 21918

Plaintiffs,

v.

BOX HILL SURGERY CENTER, LLC
100 Walter Ward Boulevard
Suite B2
Abingdon, Maryland 21009

Serve on:
L. Stephen Hess, Esq.
26th Floor
2100 East Pratt Street
Baltimore, MD 21202

and

IN THE
CIRCUIT COURT
FOR
BALTIMORE COUNTY

Case No.: 03-C-14-009238

Complaint and Demand for Jury Trial

RITU T. BHAMBHANI, M.D.
496 Rutland Drive
Fallston, Maryland 21047

Serve on:
Ritu T. Bhambhani, M.D.
496 Rutland Drive
Fallston, Maryland 21047

and

RITU T. BHAMBHANI, M.D., LLC
496 Rutland Drive
Fallston, Maryland 21047

Serve on:
Resident Agent:
Ritu T. Bhambhani, M.D.
496 Rutland Drive
Fallston, Maryland 21047

and

Barry J. Cadden
13 Manchester Drive
Wrentham, Massachusetts 02093

Serve on:
Barry J. Cadden
13 Manchester Drive
Wrentham, Massachusetts 02093

and

Gregory Conigliaro
1 Mountain View Drive
Framingham, Massachusetts 01701

Serve on:
Gregory Conigliaro
1 Mountain View Drive
Framingham, Massachusetts 01701

and

Lisa Conigliaro Cadden
13 Manchester Drive
Wrentham, Massachusetts 02093

Serve on:
Resident Agent:
Lisa C. Cadden
13 Manchester Drive
Wrentham, Massachusetts 02093

and

Douglas Conigliaro;
15 Hale Drive
Dedham, Massachusetts 02026

and

Serve on:
Douglas Conigliaro;
15 Hale Drive
Dedham, Massachusetts 02026

and

Carla Conigliaro
15 Hale Drive
Dedham, Massachusetts 02026

Serve on:
Carla Conigliaro
15 Hale Drive
Dedham, Massachusetts 02026

and

Glenn A. Chin
173 Mechanic Street
Canton, Massachusetts 02021

Serve on:
Glenn A. Chin
173 Mechanic Street
Canton, Massachusetts 02021

and

Ameridose, LLC
203 Flanders Road
Westborough, Massachusetts, 01581

Serve on:
Resident Agent:
Ameridose, LLC
203 Flanders Road
Westborough, Massachusetts, 01581

and

GDC Properties Management, LLC
701 Waverly Street
Framingham, Massachusetts 01702

Serve on:
Resident Agent:
GDC Properties Management, LLC
701 Waverly Street
Framingham, Massachusetts 01702

and

Medical Sales Management, Inc.
697 Waverly Street
Framingham, Massachusetts 01702

Serve on:
Resident Agent:
Medical Sales Management, Inc.
697 Waverly Street
Framingham, Massachusetts 01702

and

Medical Sales Management SW, Inc.
697 Waverly Street
Framingham, Massachusetts 01702

Serve on:
Resident Agent:
Medical Sales Management SW, Inc.
697 Waverly Street
Framingham, Massachusetts 01702

and

ARL Bio Pharma, Inc. D/B/A Analytical Research Laboratories
840 Research Parkway
Suite 546
Oklahoma City, Oklahoma 73104

Serve on:
Resident Agent
ARL Bio Pharma, Inc.
840 Research Parkway
Suite 546
Oklahoma City, Oklahoma 73104

and

Liberty Industries, Inc.
133 Commerce Street
East Berlin, Connecticut 06023

Serve on:
Resident Agent
Liberty Industries, Inc.
133 Commerce Street
East Berlin, Connecticut 06023

and

UniFirst Corporation (d/b/a "Uniclean Cleanroom Services")
68 Jonspin Road
Wilmington, MA 01887

Serve on:
Resident Agent
UniFirst Corporation
8820 Yellow Brick Rd.
Baltimore, MD 21237

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

COME NOW the Plaintiffs, Meghan Handy, individually, as surviving child and as Personal Representative of the Estate of Brenda L. Rozek, deceased ("Decedent"), together with

Neil E. Rozek, Kristen Lowery, Frank D. Ragan, Sr., and JoAnne Ragan, by and through their undersigned attorneys, Weitchek Mallahan Weitchek LLC, who hereby make claim against the following Defendants: Barry J. Cadden; Gregory Conigliaro; Lisa Conigliaro Cadden; Douglas Conigliaro; Carla Conigliaro; Glenn A. Chin; Ameridose, LLC; GDC Properties Management, LLC; Medical Sales Management, Inc.; Medical Sales Management SW, Inc.; ARL Bio Pharma, Inc. D/B/A Analytical Research Laboratories, Liberty Industries, Inc.; UniFirst Corporation, (d/b/a "Uniclean Cleanroom Services"); Box Hill Surgery Center, LLC, a Maryland limited liability company, Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC, a Maryland limited liability company, and allege:

I. INTRODUCTION

1. In 2012, a widespread outbreak of fungal meningitis injured people in more than 20 states and caused scores of deaths as of the time of the filing of this Complaint. At a minimum, over 751 people have been diagnosed with serious illnesses and thousands more live in fear of contracting the disease and the prospect of suffering painful injuries, testing and treatment. This preventable outbreak originated from a medication compounded and distributed by the now bankrupt New England Compounding Pharmacy, Inc. d/b/a "New England Compounding Center" ("**NECC**"). The medication was preservative free methylprednisolone acetate ("MPA") that was improperly compounded, sterilized, tested, packaged, marketed, labeled, dispensed, acquired, prescribed and administered by various entities as described below.

2. The Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") identified fungus in lots of NECC supplied injectable steroids, and specifically identified three MPA lots NECC had compounded in batch between May and August of 2012. The FDA and CDC concluded that the MPA, which was compounded at the NECC

compounding pharmacy facility in Framingham Massachusetts, was the cause of the aforementioned injuries and deaths. The NECC facilities, and especially its so called "clean room," were deplorably unclean, unsanitary and unsterile. These conditions were the source of fungus that contaminated NECC's compounded medications. The blatant disregard for even the most basic sanitary and sterility obligations by NECC, as well as its directors officers, employees, together with the wrongful conduct, omissions and activities of other actors and entities associated with or responsible for NECC's facility's deplorable condition and/or the dispensing and distribution of contaminated drugs, as described herein, together with the Health Care Providers' and other actors' identified herein woefully insufficient due diligence, vetting, inspection, testing, warning, disclosure, informed consent, overt misrepresentations, and knowing dispensing of drugs compounded under the spectre of such wrongful conduct by NECC and others, all led and substantially contributed to a national epidemic of fungal meningitis, as well as were substantial contributing factors to the Plaintiffs' Decedent's injury and resulting losses described below.

3. Multiple vials of MPA, along with other medications compounded at the NECC facilities have been recalled, but the recall was too late for Plaintiffs' Decedent, Brenda Rozek, and for many others who were injected with a fungal contaminated medicine and suffered injuries or death from one of the largest iatrogenic epidemics in United States' history.

4. The Health Care Providers named herein are a significant part of the cause of this epidemic. They, among other things, negligently selected NECC as compounding pharmacy for a difficult medication to compound in a preservative free form, and repeatedly ordered preservative free MPA in so called office supply quantities from NECC in contravention of applicable Massachusetts pharmacy dispensing laws. Among the compounded medication the

Health Care Providers obtained from NECC were eighty-five (85) 5ml vials of MPA shipped on or about August 13, 2012 that were dispensed from one or more lots of the three (3) contaminated lots MPA laden with fungus. MPA drawn from one of these vials was then, and without proper and necessary disclosure of the nature and source of the compounded medication and, further, without obtaining proper and intelligent informed consent, injected into Decedent Rozek's body on or about August 31, 2012 as part of a recommended course of pain management treatment by Health Care Provider Dr. Ritu T. Bhambhani, M.D. at the Box Hill Surgery Center. As a result of the administration of the contaminated MPA, Decedent developed a serious fungal infection that progressed into fungal meningitis, which led to her hospitalization and eventual death on September 16, 2012 at age 51.

III. PARTIES

5. Plaintiff Meghan Handy has been granted Letters of Administration declaring that she is the Personal Representative of the Estate of Decedent Brenda Lee Rozek (Maryland Estate No. 18347). Accordingly, pursuant to §7-401 of the Estates and Trusts Article of the Annotated Code of Maryland, Ms. Handy brings this Survival Action for all damages that the Decedent could have recovered had she survived.

6. Plaintiff Meghan Handy is the surviving daughter of Decedent Brenda Lee Rozek and is a resident of Cecil County, Maryland. Accordingly, pursuant to §3-904 of the Courts and Judicial Proceedings Article of the Annotated Code of Maryland, she brings this Wrongful Death Action for all damages to which she is entitled.

7. Plaintiff Neil E. Rozek is the surviving spouse of the Decedent Brenda Lee Rozek. At the time of her death, Neil E. Rozek and Brenda Lee Rozek were husband and wife and resided in Cecil County, Maryland. Accordingly, pursuant to §3-904 of the Courts and

Judicial Proceedings Article of the Annotated Code of Maryland, he brings this Wrongful Death Action for all damages to which he is entitled.

8. Plaintiff Kristen Lowery is the surviving daughter of the Decedent Brenda Lee Rozek and is a resident of Cecil County, Maryland. Accordingly, pursuant to §3-904 of the Courts and Judicial Proceedings Article of the Annotated Code of Maryland, she brings this Wrongful Death Action for all damages to which she is entitled.

9. Plaintiff Frank D. Ragan, Sr., is the surviving father of the Decedent Brenda Lee Rozek and is a resident of Cecil County, Maryland. Accordingly, pursuant to §3-904 of the Courts and Judicial Proceedings Article of the Annotated Code of Maryland, he brings this Wrongful Death Action for all damages to which he is entitled.

10. Plaintiff JoAnne Ragan is the surviving mother of the Decedent Brenda Lee Rozek and is a resident of Cecil County, Maryland. Accordingly, pursuant to §3-904 of the Courts and Judicial Proceedings Article of the Annotated Code of Maryland, she brings this Wrongful Death Action for all damages to which she is entitled.

11. Defendant Box Hill Surgery Center, LLC, (hereinafter "Box Hill Surgery Center") is a Maryland company with its principal place of business at 100 Walter Ward Blvd., Suite 300, Abingdon, Maryland 21009. At all times relevant, Defendant Box Hill Surgery Center has been engaged in the administration, staffing, supervision, and operation of a surgical practice in Harford County, Maryland, acting through actual and/or apparent agents, servants, and/or employees including, but not limited to, Ritu Bhambhani, M.D. and Ritu Bhambhani, M.D., LLC. Further, Defendant Box Hill Surgery Center regularly, continuously and systematically did business with NECC in Massachusetts by ordering compounded medications

for patients that NECC dispensed from its Framingham Massachusetts compounding pharmacy facility.

12. At all times relevant to this case, defendant Ritu T. Bhambhani, M.D., LLC, was a Maryland limited liability company with a principal office located at Dr. Bhambhani's home address of 496 Rutland Drive, Fallston, Maryland 21047, located in Harford County. According to the Maryland State Department of Assessments and Taxation, the purpose of Ritu Bhambhani, LLC, was the operation of an anesthesiology, pain management, and acupuncture practice. At all times relevant to this case, Ritu Bhambhani, M.D., LLC, was engaged in the administration and operation of an anesthesiology, pain management, and acupuncture practice in Harford County, Maryland, acting through actual and/or apparent agents, servants, and/or employees including, but not limited to defendant Ritu Bhambhani, M.D. Ritu T. Bhambhani, M.D., LLC, further regularly, continuously and systematically did business with NECC in Massachusetts by ordering compounded medications administered or to be administered to patients that NECC dispensed by mail or delivery service from its Framingham Massachusetts compounding pharmacy facility.

13. At all times relevant to this case, defendant Ritu T. Bhambhani, M.D., was a physician engaged in the practice of medicine with a primary practice area in Anesthesiology and Pain Medicine, licensed in the State of Maryland. Dr. Bhambhani's principal place of business is the Box Hill Surgery Center located at 100 Walter Ward Blvd., Suite 300, Abingdon, Maryland 21009 in Harford County, where she is the Medical Director. Dr. Bhambhani is also a resident of Harford County Maryland with an address of 496 Rutland Drive, Fallston, Maryland 21047. Upon information and belief, at all times relevant, Dr. Bhambhani was the employee/agent of defendants Box Hill Surgery Center and/or Ritu Bhambhani, M.D., LLC and was habitually engaged in the practice of medicine in Harford County, Maryland. Plaintiffs contend that at all

times relevant to this case, Dr. Bhambhani was acting within the scope of her employment/agency at the time of the alleged actions. Further, Dr. Bhambhani regularly, continuously and systematically did business with NECC in Massachusetts by ordering compounded medications administered or to be administered to patients that NECC dispensed by mail or delivery service from its Framingham Massachusetts compounding pharmacy facility.

14. Collectively Defendants Box Hill Surgery Center, LLC, Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC are referred to as "**Health Care Providers.**"

15. At all times material herein, the Health Care Providers acted by and through their respective agents, officers, employees and servants, actual, apparent or ostensible, any and all of whom were then and there acting within the course and scope or their agency, authority, duties or employment.

16. Defendant Ameridose, LLC, ("**Ameridose**") is a Massachusetts limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business at 203 Flanders Road, Westborough, Massachusetts, 01581. The managers of Ameridose are Gregory Conigliaro and Barry Cadden.

17. Defendant GDC Properties Management, LLC, ("**GDC**") is a Massachusetts limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with its principle place of business at 701 Waverly Street, Framingham, Massachusetts 01702.

18. Defendant Medical Sales Management, Inc., ("**MSM**") is a Massachusetts corporation organized and originated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Defendant Douglas Conigliaro is the President and a Director of MSM and in such capacity

actively participated in, controlled and/or directed its operations and activities. Defendant Barry Cadden is the Treasurer and a Director of MSM. Gregory Conigliaro is the Secretary and a Director of MSM.

19. Defendant Medical Sales Management SW, Inc., ("**MSMSW**") is a Massachusetts corporation organized and originated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and a Director, Barry Cadden is the Treasurer and a Director, Gregory Conigliaro is the Secretary and a Director and Lisa Conigliaro Cadden is a Director.

20. Defendant Barry J. Cadden ("**Barry Cadden**") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093, and is a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of NECC. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record, as that term is defined by Massachusetts' regulation, 247 CMR 2.00, and upon information and belief, he compounded MPA at NECC. Barry Cadden was also a founder and Manager of Ameridose and was involved in Ameridose's day-to-day operations. Barry Cadden was also the Treasurer and Director of MSM and MSMSW.

21. Defendant Gregory Conigliaro ("**Gregory Conigliaro**") is an individual person residing at 1 Mountain View Drive, Framingham, Massachusetts 01701. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, Registered Agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw operations, and regularly appeared in the NECC facility. Gregory Conigliaro is also the founder and a Manager of Ameridose and involved in Ameridose's day-to-day operations. Gregory Conigliaro is also Secretary and Director of MSM and MSMSW.

22. Defendant Lisa Conigliaro Cadden ("**Lisa Cadden**") is an individual person residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day-to-day operations of NECC.

23. Defendant Douglas Conigliaro ("**Douglas Conigliaro**") is an individual person residing at 15 Hale Drive, Dedham, Massachusetts 02026. Douglas Conigliaro is Director and President of MSM and MSMSW. Douglas Conigliaro provided advice, oversaw day-to-day operations and regularly appeared in the MSM/MSMSW facility.

24. Defendant Carla Conigliaro ("**Carla Conigliaro**") is an individual person residing at 15 Hale Drive, Dedham, Massachusetts 02026. Carla Conigliaro is one of the Directors of NECC and the wife of Douglas Conigliaro.

25. Defendant Glenn A. Chin ("**Chin**") is an individual person residing at 173 Mechanic Street, Canton, Massachusetts 02021. At least until October 2012, Glenn Chin was a pharmacist at NECC. Chin, upon information and belief, compounded drugs, including MPA, at NECC.

26. Defendant Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Chin, Ameridose, LLC, GDC Properties Management, LLC, Medical Sales Management, Inc., Medical Sales Management SW, Inc., are sometimes collectively referred to as the "**NECC Related Parties.**"

27. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("**ARL**") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principle place of business at 840 Research Parkway, Suite 546, Oklahoma

City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

28. Defendant Liberty Industries, Inc. ("**Liberty**") is a Connecticut corporation with its principal place of business at 133 Commerce Street, East Berlin, Connecticut 06023. Liberty designs, manufactures, distributes, and installs cleanrooms and contamination control supplies both in the United States and worldwide. Liberty manufactured, constructed, installed, and/or designed all NECC and Ameridose cleanrooms at the Framingham, Massachusetts facility. The cleanrooms manufactured, constructed, installed and/or designed for NECC and/or Ameridose contained defects that made them unsuitable for their intended use and were a direct and proximate cause of injury to Decedent.

29. Defendant UniFirst Corporation d/b/a "Uniclean Cleanroom Services" ("**UniFirst**") is a corporation duly organized and existing under and by virtue of the laws of the State of Massachusetts, with its principal place of business located at 68 Jonspin Road, Wilmington, MA 01887 and place of business in Baltimore County, Maryland at 8820 Yellow Brick Road, Baltimore, MD 21237. "UniClean" is a division of UniFirst. UniFirst's corporate mission is to be recognized as the quality leader in the cleaning and garment industry. UniFirst also represents that its services will "improve the safety and cleanliness" of a business facility when hired to perform services there. UniFirst at all material times contracted with NECC to provide cleaning services, including cleaning the "cleanrooms" used to manufacture and/or compound drugs, including NECC Contaminated Drugs.

30. At all times material herein, all Defendants acted by and through their respective agents, officers, employees and servants, actual, apparent or ostensible, any and all of whom

were then and there acting within the course and scope or their agency, authority, duties or employment.

IV. JURISDICTION AND VENUE

31. Jurisdiction is proper in that many of the materials actions as well as the tortious harm occurred here in Maryland.

32. Venue for this action is proper in Baltimore County, as Defendant UniFirst does business under the trade name "Uniclean" and many place of business in Baltimore County, Maryland at 8820 Yellow Brick Road, Baltimore, MD 21237.

33. This case was originally filed in the Health Care Alternative Dispute Resolution Office of Maryland, and subsequently transferred to this Court as evidenced by the attached Order of Transfer.

V. FACTS COMMON TO ALL COUNTS

NECC's Chapter 11 Bankruptcy Proceeding

34. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code which is pending and captioned as *In re: New England Compounding Pharmacy, Inc., Debtor*, United States Bankruptcy Court for the District of Massachusetts Case No. 12:19882 HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate.

35. This case is related to NECC's Bankruptcy case because the prosecution and/or outcome of the proceeding could have an effect on the bankruptcy estate.

36. Upon information and belief, (i) NECC has express contractual indemnification obligations to among others, the NECC Related Parties, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Douglas Conigliaro, Glenn Chin, GDC, MSM and MSMSW, (ii)

some if not all of the aforementioned individuals are insureds under NECC's insurance policies and (iii) NECC and the NECC Related Parties, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Douglas Conigliaro, Glenn Chin, GDC, MSM and MSMSW, all have contribution, indemnification and/or other reimbursement claims against as against each other.

37. Adversary proceedings seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC's bankruptcy against several of the NECC Related Parties (Barry Cadden, Lisa Cadden, Gregory Conigliaro, Carla Conigliaro, GDC, and MSM).

Multi-District Litigation Proceedings

38. Lawsuits alleging death or injury based on contaminated MPA have been filed around the country. On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings (the "MDL Court"). The transferred actions are pending in the MDL Court in the Multidistrict Litigation action styled: *In re: New England Compounding Pharmacy, Inc. Products Liability Litigation*, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS. The transferred cases have been assigned to the Honorable Rya W. Zobel, United States District Judge, for pre-trial proceedings and coordination. This case is a related case to those and subject to transfer to the MDL per order of the MDL Court relating to transfer of cases related to the NECC MDL and Chapter 11 Bankruptcy.

NECC's compounding operations and activities of the NECC Related Parties, ARL, Liberty and UniClean

39. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to pharmacies in many states throughout the United States, including Maryland.

40. Upon information and belief, NECC was a privately-held company that was owned and controlled by Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro, Barry Cadden, and Lisa Cadden. At all times material these parties had the ability and power to affect changes and corrective actions relating to NECC's conduct and omissions that are relevant to this matter.

41. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was also NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications, including MPA, at NECC.

42. "Manager of Record" or "Pharmacist Manager of Record," as defined by Massachusetts Regulation, 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

43. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).

44. At least until October 2012, Gregory Conigliaro was involved in co-managing the day-to-day operations of NECC, MSM, MSMSW, Ameridose, and GDC. At all times material

herein he had the ability and power to affect changes and corrective actions relating to these entities' conduct and omissions that are relevant to this matter.

45. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications, including MPA, at NECC. She also was involved in the management of NECC and had the ability and power to affect changes and corrective actions relating to NECC's conduct and omissions that are relevant to this matter.

46. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications, including MPA, at NECC. At all times material herein Chin had the ability and power to affect changes and corrective actions relating to NECC's conduct and omissions that are relevant to this matter, and/or or take reasonable steps and measures to prevent or ameliorate any harm happening to consumers by NECC's conduct and omissions that are relevant to this matter.

47. According to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, Ameridose is a "distribution center to entities of common ownership - currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

48. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC. In 2005, NECC hired and paid Sophia Pasedis, a member of the Massachusetts Board of Registration in Pharmacy, to consult with NECC on the formation and establishment of Ameridose.

49. On April 11, 2011, Ameridose employee, Michelle Rivers, upon information and belief and at the direction of the NECC principals, requested certification for pharmacy

technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

50. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact "mlord@medicalsalesmgmt.com." Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC's principals.

51. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

52. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including MPA. One former employee of MSM and/or MSMSW has reportedly stated: "I didn't think there was any difference [between Ameridose and NECC]."

53. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

54. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

55. According to ARL's Internet website, "ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry."

56. According to ARL's Internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."

57. ARL also states on its Internet website that it follows "USP monographs/general chapters[,]" and that it has a formal Quality Assurance Program in compliance with "USP monographs/general chapters[.]"

58. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: "[y]our customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. *You should expect nothing less from the testing laboratory you entrust.*" (*Emphasis is original*).

59. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL's **"[t]esting methods and technologies [are] unparalleled in the market today[.]"** (*Emphasis in original*).

60. Upon information and belief, ARL provided and was paid for sterility testing services and information to NECC for its compounded medications, including MPA.

61. With respect to its sterility tests, ARL, on its Internet website, states: "We examine each sterility test for growth at days 2, 3, 7 and 14 and log the results. If a test shows no

evidence of microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation."

62. At all times material herein, ARL knew or had reason to know that (a) its testing and test results relating to NECC products, including MPA, were commissioned and intended for the protection of patients who were to be administered NECC's compounded medications; (b) that its test results would be relied upon and used by NECC in dispensing the medication to doctors and medical facilities ordering and administering NECC's medications; (c) that doctors depended upon and would rely on ARL's test results in determining to administer NECC's compounded medications; and (d) NECC would distribute or share ARL's test results with physicians and/or hearth care facility decision makers in connection with NECC's marketing and/or dispensing of its compounded medications, including MPA.

63. GDC, whose name is an acronym for "Gregory D. Conigliaro," owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

64. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

65. In an online posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC describes one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state …rules and regulations."

66. GDC maintained and/or exercised a high degree of control over the premises leased by NECC.

67. Liberty manufactured, constructed, installed, and/or designed all NECC and Ameridose cleanrooms at the Framingham, Massachusetts facility. The cleanrooms manufactured, constructed, installed and/or designed for NECC and/or Ameridose contained defects that made them unsuitable for their intended use and were a direct and proximate cause of injury to Plaintiffs.

68. UniFirst at all material times contracted with NECC to provide cleaning services, including cleaning the "cleanrooms" used to manufacture and/or compound drugs, including NECC Contaminated Drugs.

The 2012 MPA Fungal Infection Epidemic

69. MPA is a steroid medication that is used, *inter alia*, to treat joint, neck and back pain. MPA is commonly administered via spinal-area injection to patients with neck and back pain.

70. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden and Glenn Chin compounded, tested, marketed, dispensed and/or distributed MPA, including a purported preservative free sterile version that is difficult to compound and carries substantial risks of contamination, adulteration and/or misbranding.

71. GDC and Gregory Conigliaro knew that NECC was compounding MPA, including a purported preservative free version, at NECC's 697 Waverly Street facility, and further knew that this medication was injected into humans and was required to be sterile.

72. Until October 2012, NECC compounded MPA, including a preservative free version, at its facility in Framingham, Massachusetts, and NECC sold MPA, including a preservative free version, to health care providers in more than 20 states across the country,

including to Box Hill Surgery Center in Maryland, directly and/or through Ameridose, MSM and/or MSMSW

73. On September 21, 2012, the CDC was notified by the Tennessee Department of Health of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.

74. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and is usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

75. According to the CDC, symptoms for meningitis include the following: new or worsening headache, fever, sensitivity to light, stiff neck, new weakness or numbness in any part of the body, slurred speech and increased pain, redness or swelling at the injection site. Death may result from meningitis.

76. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients may just exhibit one or two of these symptoms.

77. On or about September 26, 2012, NECC recalled the following lots of methylprednisolone acetate (PF) 80mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013. The

"PF" denotes preservative free. The number in the Lot# denotes the date of the lot's compounding.

78. The FDA identified Box Hill Surgery Center in Maryland as one of the Health Care facilities that received vials of MPA that were subject to the September 2012 recall. Box Hill Surgery Center is also the location where Decedent Rozek was injected with NECC's MPA on or about August 31, 2012. On information and belief, Decedent was administered MPA from one of NECC's recalled lots.

79. On information and belief, including the purported prescription record provided by Box Hill Surgery Center, on or about August 13, 2012 Box Hill Surgery Center nurse Andrew Vickers, R.N. faxed to NECC Massachusetts' compounding pharmacy a NECC Prescription Order form for eighty-five (85) five(5) milliliter vials of - eighty (80) mg/ml strength dosage preservative free MPA. The prescription order states further under the column Name of Patient: "See Attachment of Pt names" and "1 patient/per 5 vials." No attachment containing Decedent Rozek's name has been produced to Plaintiffs despite requests to Box Hill Surgical Center for all prescription records relating to Decedent. NECC records available on the FDA's website indicate NECC shipped the vials ordered by Box Hill to it on the same day, August 13, 2012. Decedent's name does not appear on any prescription form submitted to NECC relating to the MPA dispensed and administered to her at Box Hill Surgery Center on or about August 31, 2012, which is consistent with the fact that until August 20, 2012 she had had never before visited Box Hill Surgery Center or was seen and attended to by Dr. Bhambhani. It was during this August 20, 2012 clinical visit that Dr. Bhambhani, following obtaining Decedent's medical history and a physical examination, recommended to Decedent she undergo a cervical epidural steroid

80. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."

81. In NECC's October 6, 2012, press release, NECC advised that it was "notifying its customers of this recall by fax[,]" and that "[c]linics, hospitals and Health Care providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice." It was subsequent to this event that Plaintiff was first made aware by the Health Care Providers that she had been administered NECC's contaminated steroids medications. Prior to this time she was reasonably unaware of this.

82. In NECC's October 6, 2012, press release, NECC explained that "[p]roducts from NECC can be identified by markings that indicate New England Compounding Center by name or by its acronym (NECC), and/or the company logo.

83. In addition, as the CDC, and other health care authorities, practitioners and commentators monitored and reported on developments in the exposed patient community, it was discovered that the problems associated with patient injections from the three recalled MPA lots are manifold, latent, insidious and long lasting, including: (a) an outbreak of localized spinal or paraspinal infections at or about the site where the MPA steroid was injected; (b) infections associated with injections into a peripheral joint space, such as a knee, shoulder, or ankle; and (c) delayed manifestation, recrudescence and relapse of diagnosed fungal meningitis and spinal, paraspinal and joint space infections and abscesses.

84. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.

85. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin agreed to voluntarily cease their practice as pharmacists until at least December 31, 2012. Lisa Cadden also has agreed to voluntarily cease her practice as a pharmacist until at least December 31, 2012. Upon information and belief, none of them have practiced as a pharmacist since voluntarily ceasing their practice.

86. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

87. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

88. From May, 2012 through August 2012, NECC sent several samples of its methylprednisolone acetate to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC in one lot on May 21, 2012.

89. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

90. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

91. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

92. On or about August 10, 2012, NECC caused one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials from Lot #08102012@51, BUD 2/6/2013.

93. The Microbiology Reports issued by ARL to NECC between May, 2012 and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were to be conducted in compliance with USP 71.

94. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

95. ARL was well aware of the sterility risks posed by compounding pharmacies, specifically including the sterility risks posed by NECC's compounding practices.

96. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

97. In 2005, ARL's Chief Executive Officer, Thomas Kupiec ("Kupiec"), wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

98. In 2007, Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

99. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding[,]" which stated that there had been "more than 200 adverse events involving 71 compounded products since 1990. Some of these instances had devastating repercussions." All Defendants either knew or had reason to know of this FDA guidance publication.

100. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to be tested in relation to the number of articles in the batch" and a "14-day quarantine of the drug to await final test results[,]" Kupiec wrote in a 2007 published article that there should be "separate standards for compounding pharmacies and manufacturers."

101. While the requirements of USP 71 were not relaxed for compounding pharmacies after Kupiec's 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

102. On information and belief, other testing laboratories that perform sterility testing on drugs compounded by compounding pharmacies request double the number of samples required by USP 71.

103. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded findings of numerous microbiological isolates (bacteria and mold) within the so called "Clean Room" at NECC's facility used for the production of MPA. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin knew or should have known of these findings.

104. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to investigate the findings, cause(s) and source(s) of these isolates and made no effort to identify the isolates.

105. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to perform any product assessments for the products made in the "Clean Room" where the isolates were found.

106. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to take any corrective actions or measures with regards to the isolates that were found.

107. Despite the findings of these isolates, NECC continued to compound preservative free MPA, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

THE NECC RELATED PARTIES IGNORED SAFETY STANDARDS BY PRODUCING DRUGS IN A NON-COMPLIANT FACILITY

108. The Massachusetts Department of Public Health and FDA investigators identified serious deficiencies and significant violations at NECC that placed the public's health and safety at risk. Each Agency has released reports on Defendants' longstanding widespread disregard for safety. Some examples follow. The conditions were so bad, the FDA issued a Form 483 identifying eight pages of observed conditions or practices that may indicate violations of the Federal Food, Drug and Cosmetic Act, or related regulations. The findings reveal repulsive conditions where bacteria and mold fester throughout the NECC facility and equipment.

109. In early October 2012, FDA investigators located fungal contamination in a sealed vial of MPA at NECC's facilities on GDC's property. The FDA's findings prompted NECC to recall 17,676 single-dose vials of MPA.

110. Even though NECC recalled the MPA in early October, thousands (estimated to be over 14,000) of people at outpatient clinics and similar facilities in more than 20 states were injected with the steroid between July and September 2012, including Decedent Rozek.

111. The Massachusetts Department of Public Health ("DPH") investigators, in collaboration with investigators from the FDA, investigated NECC and released preliminary findings on October 23, 2012.

112. As an initial matter, the DPH stated: "[u]pon beginning the joint on-site investigation of NECC early in this outbreak, DPH and FDA investigators identified serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk."

113. In its preliminary findings the DPH found: "[d]uring the facility inspections, investigators documented serious health and safety deficiencies related to the practice of pharmacy." The DPH noted:

a. NECC distributed two of the recalled lots of methylprednisolone acetate (PF) 80 MG/ML prior to receiving results of sterility testing:

a. Lot 06292012@26 was prepared on June 29, 2012. Final sterility testing was completed on July 17, 2012. Two shipments of product were made prior to the final sterility tests results being received.

b. Lot 08102012@51 was prepared on August 10, 2012. Final sterility testing was completed on August 28, 2012. Eleven shipments of product were made prior to the final sterility tests results being received.

b. Final sterilization of product did not follow proper standards for autoclaving (sterilization through high pressure steam) pursuant to United States Pharmacopeia Standard 797 ("USP 797") and NECC's own Standard Operating Procedures. Examination of NECC records indicated a systemic failure to keep products in the autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

c. NECC did not conduct proper validation of autoclaves pursuant to USP 797. NECC failed to test their autoclaves to ensure proper function.

d. Visible black particulate matter was seen in several recalled sealed vials of methylprednisolone acetate from Lot 08102012@51.

e. Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation, within the sterile compounding area were not thoroughly cleaned pursuant to USP 797. Residual powder was visually observed within the hood during inspection. This contamination may subsequently lead to contamination of compounded medications.

f. Condition of "Tacky" mats, which are used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry, violated the USP 797. Mats were visibly soiled with assorted debris.

g. A leaking boiler adjacent to the requisite clean room created an environment susceptible to contaminant growth: "A pool of water was visually observed around the boiler and adjacent walls, creating an unsanitary condition; the culture results of this potential contaminant are still pending."

114. The inspection reports further revealed that surface samples from NECC's "clean" rooms found bacterial and mold, as did samples of various equipment and parts of the facility. Air sampling showed "1 big mold" as far back as May 29, 2012. Air sampling taken throughout the facility also found mold and bacteria present. Dozens of results exceeded the "action level." "There was no investigation conducted by the firm when levels exceeded their action limits and there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacterial and mold) from the facility."

115. Inspectors also noted in their reports on NECC: Environmental monitoring procedures and practices require sampling. Records showed mold and bacteria. "These results were not investigated and there was no identification of the isolates. There were no product impact assessments performed for any sterile products that were made in the hoods or glove boxes on the days the samples were taken. In addition, the firm has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products."

116. FDA reports indicate there were observations of greenish yellow discoloration lining the interior surface of the viewing lens within the "Inside" autoclave used for steam sterilization of various components and equipment (e.g. vials of multiple sizes, stoppers, and spin

bars) used in the formulation and packaging of sterile drug products. The FDA further observed condensation along the interior surfaces of the "Outside" autoclave to collect in a pool at the base of the chamber.

117. The investigators also observed problems with NECC's ability to maintain its clean room, which is an enclosed space that is supposed to be designed and maintained to have a controlled environment with low levels of airborne particles and surface contamination. Production of sterile drug products in a properly functioning and maintained clean room reduces the risk of microbial contamination.

118. The site of NECC's production facility signaled potential contamination risks and hazards. A used mattress processing facility, also owned by the Conigliaro family, abuts and operates under the same roof as NECC's drug compounding facility. As the FDA noted in its inspection, "[t]he firm is abutted to the rear and along the left parking area by a recycling facility that handles such materials as mattresses and plastics. On 10/02/2012, the area was observed to include large equipment (e.g. excavators and freight trucks) producing airborne particulates (e.g. dust). Rooftop units serving the [NECC] firm's HVAC system were estimated to be located approximately 100 feet from the recycling facility."

119. The FDA observed what appeared to be white filamentous substances covering the HVAC return located behind the autoclave located in the firm's Middle Room (purportedly an ISO level 7 space). This autoclave is used for the steam sterilization of formulated bulk drug suspensions. The FDA further observed greenish residue covering the surface of the ceiling exposed to the filter above, within Weigh Station 3 Hood located in the firm's purported ISO 6 "Clean Room." The firm uses Weigh Station Hoods to weigh active ingredients and other raw materials utilized in the formulation of sterile drug preparations.

120. In sum, FDA observed bacteria and mold growing all over the firm's "sterile" facility, one which NECC repeatedly represented to customers was "state-of-the-art" and used to produce "highest quality compounded medications."

121. MSM and/or MSMSW marketed, Ameridose distributed and ARL certified the sterility of the NECC products that were compounded in such deplorable conditions.

122. Liberty negligently and defectively designed, installed and repaired NECC's clean rooms and contributed to the existence of the unclean and unsatisfactory conditions at NECC, thereby contributing to the contamination of the MPA compounded by NECC.

123. UniFirst negligently cleaned NECC's cleanroom and in the course of same was aware of the chronic and unclean and unsatisfactory conditions at NECC, which it failed to properly clean and, importantly, failed to notify appropriate management and/or regulatory bodies of the chronic problem; thereby contributing to the contamination of the MPA compounded by NECC and/or the dispensing of contaminated medications.

THE NECC RELATED PARTIES DISREGARDED PRIOR COMPLAINTS AND INSPECTIONS BY CONTINUING IMPERMISSIBLE CONDUCT AND IGNORING SAFETY RISKS

124. The NECC Related Parties effectively ignored dozens of complaints and warnings signs of hygiene and sterility problems from as early as April 1999.

125. In 2002, two patients suffered an adverse effect after taking an NECC compounded steroid used to treat joint pain and arthritis. One victim subsequently died. The FDA notified the Massachusetts' pharmacy board in October 2002 about an incident involving a drug the company had produced, methylprednisolone acetate, which is the same steroid that caused the current fungal meningitis and other associated disease outbreak in 2012.

126. In 2004, an inspection report revealed that a toxin had been found in an NECC drug and that the company could not produce various records about the drug, including test results on its sterility. NECC and other Defendants failed to meet accepted standards that year for making the same steroid as involved herein.

127. A 2006 letter to NECC from Pharmacy Support Inc., an outside evaluation firm, observed that the company continued to have significant gaps in its sterile compounding operation. That same year the FDA issued warning letters to NECC. NECC and other Defendants received other warnings as well.

128. NECC and the NECC Related Parties solicited, permitted or facilitated and/or aided and abetted the solicitation of, out-of-state prescriptions for office use and used unapproved forms. NECC and the NECC Related Parties were aware of complaints regarding this practice and its improper promotional material and methods, but turned a blind eye to it all.

THE HEALTH CARE PROVIDERS EXPOSED DECEDENT BRENDA ROZEK TO TOXIN CONTAMINATED NECC COMPOUNDED MPA

129. Between May and September of 2012, the NECC Related Parties caused 435 vials of preservative free methylprednisolone acetate to be shipped to Box Hill Surgery Center's medical practice and facility in Abingdon, Maryland which were part of the three lots of contaminated preservative free MPA recalled by NECC. Thousands of other contaminated vials were shipped to scores of other clinics across the country.

130. Massachusetts law and regulations require patient specific prescriptions in order for a Massachusetts compounding pharmacy such as NECC to legally compound, fill and dispense a medication prescription regardless of the location of the patient or prescriber. Massachusetts law prohibits selling and dispensing compounded medications pursuant to so called "office supply" quantity prescriptions.

131. The NECC Related Parties were aware of Massachusetts compounding laws and regulations but negligently, recklessly or intentionally took, authorized, permitted, failed to stop or otherwise aided and abetted NECC's disregard, violation and circumvention of applicable Massachusetts law and regulations, by directing or allowing prescribers or health care providers to supply false or fabricated prescription forms in connection with obtaining NECC's compounded MPA and other prescription drugs. In the course of so doing these parties further agreed expressly, impliedly or tacitly with various NECC Related Parties named herein, to engage in overt, purposeful and malicious acts that violate or circumvent applicable Massachusetts pharmaceutical law and regulations.

132. The Health Care Providers were aware of these Massachusetts compounding laws and regulations but negligently, recklessly or intentionally took, authorized, permitted, failed to stop or otherwise aided and abetted NECC's disregard, violation and circumvention of applicable Massachusetts law and regulations, by, among other things, supplying, directing or allowing prescribers or other health care providers or administrative staff to supply false, bogus or fabricated prescription forms in connection with obtaining NECC's compounded MPA and other prescription drugs. In the course of so doing these parties further agreed expressly, impliedly or tacitly with various health care providers, including the Health Care Providers named herein, to engage in overt, purposeful and malicious acts that violate or circumvent applicable Massachusetts pharmaceutical law and regulations.

THE HEALTH CARE PROVIDERS' TREATMENT AND CARE OF DECEDENT BRENDA ROZEK

133. On or about August 20, 2012, Decedent Rozek came under the medical care and treatment of the Health Care Providers in connection with complaints of neck and left arm pain, which Dr. Ritu T. Bhambhani, M.D., determined and diagnosed were secondary to cervical disc

protrusion, cervical spondylitis and cervical radiculopathy. At such time, and thereafter at all times material herein as well, she was attended to, diagnosed, managed and treated by physicians and other health care providers employed by Box Hill Surgery Center and/or Ritu T. Bhambhani, M.D., LLC, including Dr. Ritu T. Bhambhani, M.D. Based on her condition, complaints, signs, symptoms and diagnosis, Dr. Bhambhani on that date recommended and prescribed to Decedent that she undergo an epidural steroid injection. Decedent agreed and the procedure at that time was scheduled for August 31, 2012 at Box Hill Surgery Center.

134. During all relevant times, Dr. Bhambhani managed Box Hill Surgery Center and/or Ritu T. Bhambhani, M.D., LLC. She also was an agent, servant and employee of these entities, acting within the course and scope of her authority, duties and employment.

135. During all relevant times Dr. Bhambhani participated in Box Hill Surgery Center and/or Ritu T. Bhambhani, M.D., LLC.'s decision to prescribe, purchase for resale, dispense to patients and administer NECC's compounded preservative free MPA – in contrast to medications manufactured and distributed by FDA approved and regulated manufacturers – to patients treated in Box Hill Surgery Center, including Decedent Rozek.

136. During all relevant times the Health Care Providers knew or should have known of the dangers of using compounded preservative free steroid drug formulations instead of such drugs that were manufactured by FDA approved manufacturers, and specifically were aware of or had reason to know of the risks and dangers of using drugs compounded by NECC. The dangers, hazards and problems entailed in administering compounded drugs, and especially the use of preservative free sterile preparations, were known to the medical profession and the subject of articles and professional guidance documents.

137. NECC competed in the medical marketplace on the basis of offering cheaper prices for MPA and other drugs. Such factor and consideration is believed, and therefore alleged, to have entered into and was one of the factors prompting the Health Care Providers to either obtain, or to decide and direct Box Hill Surgery Center to obtain, preservative free MPA from NECC instead of other available manufactured steroid preparations, or, alternatively, obtaining compounded MPA from local pharmacies where it could have readily visited, inspected and monitored the quality and safety of the MPA being compounded for use in epidural steroid injection ("ESI") procedures performed by the Health Care Providers at the Box Hill Surgery Center's Maryland facility.

138. Despite the existence of professional organizations and societies that provide inspections, assessments and accreditation certifications for compounding pharmacies, NECC was not accredited by any such organization.

139. In connection with the Health Care Providers obtaining NECC's preservative free MPA for its patients, including Decedent Rozek, they either failed to take or negligently performed reasonable and necessary due diligence and investigatory steps and measures necessary to vet, evaluate and determine the safety and quality of NECC's products, and, in particular, determine if NECC could properly and suitably compound, package and provide to them sterile preservative free MPA for use in ESI procedures, including the ESI procedure performed on Decedent Rozek on or about August 31, 2012.

140. On or about August 31, 2012, Dr. Bhambhani, at Box Hill Surgery Center's facility performed a cervical epidural steroid injection under fluoroscopic guidance procedure on Decedent, during which procedure Decedent was administered, according to her medical records, NECC's preservative free MPA. The MPA used during the ESI procedure – falsely identified in

Dr. Bhambhani's operative report regarding the procedure performed on Decedent as preservative free "DepoMedrol", which is a brand name of an FDA approved manufactured product – was drawn from a vial that was part of the three lots of fungus contaminated MPA vials that NECC recalled on or about September 26, 2012 due to fungal contamination traced back to it by the CDC following the discovery of the fungus meningitis outbreak.

141. At no time prior to the ESI procedure performed on Decedent did the Health Care providers disclose, advise or inform Decedent that the steroid medication going to be injected into her body was not a medication manufactured by an FDA approved and inspected manufacturer, such as brand name or an FDA approved AB generic of DepoMedrol, but rather was a medication that the Health Care Providers had obtained via mail order from a pharmacy in Massachusetts that was neither inspected by the FDA nor accredited by any valid compounding pharmacy accrediting body. Such information is and was objectively material information to a reasonable patient's decision to undergo an ESI procedure using such medication.

142. Following her ESI procedure on August 31, 2012, the fungus contaminated MPA caused Decedent to sustain and suffer a fatal injury to her body, fungal meningitis. She eventually began to experience progressively worsening pain and other debilitating signs and symptoms of fungal meningitis. That led her to being seen in the Emergency Room of Union Hospital, Elkton, Maryland and thereafter admitted to Union Hospital for diagnosis and treatment on an inpatient basis. As her condition deteriorated and became more extreme, she was transferred to John Hopkins Hospital, in Baltimore, Maryland, where after extensive tests and efforts at treatment she succumbed to her contaminated medication induced injury and disease on September 16, 2012.

Liberty Industries, Inc.'s Deficient Cleanrooms

143. Liberty is a designer, manufacturer, distributor and installer of cleanrooms and contamination control supplies both in the United States and worldwide.

144. In 2005, 2006 and 2008, Liberty manufactured, constructed, installed, and/or designed an ISO Class 7, ISO Class 6, and an ISO Class 5 cleanrooms ("the Cleanrooms"), respectively, for NECC and/or Ameridose at the Framingham, Massachusetts facility.

145. Upon information and belief, subsequent room additions, rework or repair (warranty or otherwise), and/or system upgrades, done by Liberty, took place within each of these Cleanrooms after certification had been issued.

146. The Cleanrooms manufactured, constructed, installed and/or designed for NECC/Ameridose contained defects that made them unsuitable for their intended use. Liberty owed a duty to Plaintiffs, to manufacture, construct, install, and/or design the NECC/Ameridose Clean rooms in such a manner as to prevent the contamination of pharmaceuticals compounded within them.

147. Liberty knew, or reasonably should have known, that the Cleanrooms were defective upon certifying them ready to use and/or upon inspecting the premises after certification and/or upon subsequent addition, rework or repair of the Cleanrooms.

148. Upon further information and belief, one or more of the Cleanrooms was designed with, manufactured, constructed and/or had installed faulty ceiling grids and/or used improper materials in addition to other deficiencies creating a cleanroom environment prone to pressure inconsistencies, water damage and other failings that would disrupt or destroy the cleanliness of the Cleanrooms and making them susceptible to contamination.

149. Upon information and belief, on numerous occasions, NECC requested and was denied repair of Liberty's defective work. In at least one cleanroom designed and installed by

Liberty, a large opening in the wall provided access to a conveyor belt covered only with hanging vinyl slats. This opening provided a means of potential contamination and made it difficult to maintain the required negative air pressure.

150. Further, upon information and belief, Liberty had actual and/or constructive knowledge of the deficiencies in the design, manufacture, construction, and installation of the Cleanrooms, such that products compounded within them were subject to contamination.

151. One or more of the Cleanrooms were used to compound the NECC Contaminated Drugs administered to Decedent.

152. The defective manufacture, construction, installation, and/or design of the Cleanrooms, and Liberty's failure to remedy the defects despite its actual and/or constructive knowledge of those deficiencies, caused Plaintiffs' Decedent to suffer damages, including, but not limited to, expenses associated with the treatment of fungal meningitis and other illnesses. The defects were the direct, proximate, and foreseeable cause of damages incurred by Plaintiffs' Decedent.

153. Had Liberty exercised its duty to exercise reasonable conduct by properly manufacturing, designing, and certifying the Cleanrooms, Plaintiffs' Decedent would not have suffered the damages complained of herein.

UniFirst Corporation Deficient Cleanroom Cleaning Services.

154. UniClean Cleanroom Services is a division of Defendant UniFirst Corporation. UniFirst holds itself out as a service provider delivering value-added services and products to, among other industries, the medical device, pharmaceutical, and other industries that utilize cleanroom controlled environments. UniFirst represents that it offers comprehensive cleanroom cleaning and maintenance programs to help ensure that facilities are operating within specified classification goals.

155. UniFirst itself and/or through UniClean, touts its expertise to companies like NECC and Ameridose. UniFirst knows that particulates in cleanrooms are deposited onto surfaces such as floors, walls, work surfaces and machinery, and that these particulates may cause increases in manufacturing and product compounding reject rates. UniFirst, its agents, employees, representatives, and UniClean workers have, for many years, had actual knowledge that visible and non-visible particulate loads can also lead to product contamination safety concerns for end users. In its marketing materials Unifirst acknowledges that to reduce these risks, it is imperative that an effective cleanroom cleaning program be implemented and maintained. UniFirst claims to follow stringent cleaning procedures and claims to employ highly-trained technicians as key components in eliminating such contamination threats.

156. At all times mentioned herein and material hereto, UniFirst held itself and its agents, servants, workers, representatives, personnel, and employees out to be skillful and qualified to deliver quality services and products and through the highest standards. Indeed, UniFirst itself and/or UniClean, represents that it is an ISO 9001: 2008 registered company offering services that include sterile and non-sterile garment services, and contamination control including cleanroom cleaning, fogging and environmental monitoring, among other services.

157. UniFirst recognizes the dangers associated with contaminated cleanrooms. In the company's own marketing materials, it acknowledges that "80% of the dirt and grime that enters your building is tracked in on the shoes of employees and visitors." UniFirst knows that any contract for services or products entered into with any company such as NECC or Ameridose has a direct benefit for customers, who are the intended beneficiaries of such contracts. For example, UniFirst has stated on its website and in marketing materials that over 70% of customers say that a poorly maintained facility "is enough reason not to patronize a business again," and that by

hiring UniFirst, a company's "business image will remain spotless, and your customers and employees will know you care."

158. UniFirst markets its products and services aggressively, and represents that, among other things, "[t]o help with your infection control efforts, UniFirst delivers fresh mops and wipers and picks up your soiled ones on a regular schedule. We maintain inventory, perform hygienic laundering, and replace any worn out items."

159. UniFirst entered into a Contamination Control Service Agreement ("CCSA") with NECC on October 7, 2008, and renewed it thereafter, such that a contract existed in calendar years 2011 and 2012.

160. According to the terms of the CCSA and later iterations, UniFirst agreed to furnish services with supporting materials necessary for the performance of its duties, which expressly included cleaning each Cleanroom at the NECC facilities. UniFirst's duties were outlined in a Service Schedule attached and incorporated into the CCSA first signed and thereafter in force and effect. UniFirst's duties included cleaning and sanitizing each anteroom and cleanroom. The areas to be cleaned and sanitized by UniFirst employees included but were not limited to the floors, ceilings, and hoods of each room. UniFirst agreed to a triple decontamination process for each room, using products provided by UniFirst.

161. UniFirst agreed that, among other things, it would specifically provide its staff with cleanroom training and training regarding NECC's Standard Operating Procedures.

162. UniFirst performed services and sold products to NECC each month, from calendar year 2010 through September 2012, and UniFirst invoiced NECC for services rendered.

163. During the stated time frame, UniFirst failed to meets its own written standards in performing its contractual duties, allowing the contamination of the cleanrooms UniFirst was

entrusted to clean in the following ways: (A) UniFirst employees, contractors and/or representatives, including those within the UniClean division, entered the NECC facilities (including the anterooms) in street clothes, without donning sterile or contaminant-free such as shoe covers, hair caps, coveralls, and gloves that were readily available at the NECC facilities; (B) UniFirst employees, contractors and/or representatives brought into the NECC anterooms and cleanrooms cleaning equipment, including mops, mop heads, sponges and buckets that had been moved through exterior environments, even though such equipment had not been sanitized by or cleaned appropriately, allowing contamination to occur throughout various parts of the NECC facility; and (C) UniFirst employees, contractors and/or representatives failed to clean or wipe shoes, boots and other footwear on floor mats used in the room entry process, thereby allowing contaminants into and throughout the NECC facility.

164. UniFirst had actual knowledge of the dangers of bacteria, mold and other microorganisms. UniFirst knew or should have known that such contaminants - if not eliminated - would expose patients and end use consumers such as Plaintiff, to contamination of products produced by NECC in its cleanrooms.

165. UniFirst had actual knowledge of the very mold that was ultimately found in the NECC facility. In a "white paper" found on the www.unifirst.com website, UniFirst identifies *aspergillus niger* as a "mold" that grows when garments are contaminated. In the white paper UniFirst acknowledges that this mold represents one of the most common types of microorganism contaminants found in facilities like the NECC location.

166. *Aspergillus niger* was found or brought into in the NECC facility. UniFirst failed to perform the job it was hired to do.

167. As a result of failures and omissions, UniFirst (solely or in concert with NECC) negligently allowed contaminants such as *aspergillus* into every cleanroom where recalled products were made, composed, mixed, prepared, packaged and stored.

168. UniFirst, its agents, and employees knew or should have known of the dangers of allowing contaminants into the NECC facility, including its anterooms and cleanrooms. UniFirst did not conduct appropriate due diligence to follow its own policies and procedures, and failed to follow NECC policies and procedures when in that facility.

PERTINENT MARYLAND AND MASSACHUSETTS LAW

169. The Code of Maryland Regulations (hereinafter "COMAR") provides quality of care licensing standards for health care providers and facilities that are licensed by the Office of Health Care Quality. Under Title 10 Department of Health and Mental Hygiene Subtitle 05 Freestanding Ambulatory Care Facilities, 10.05.01.06 (D) Policies and Procedures, the administrator, in consultation with the medical director, shall develop and implement policies and procedures governing the operation of the facility which include at a minimum: ...(8) Infection control for patients and staff; ... E. The administrator shall ensure that all: ... (3) Appropriate personnel implement all policies and procedures as adopted.

170. COMAR 10.05.05.10 Pharmaceutical Services provides: A. The freestanding ambulatory surgical facility shall: (1) Provide drugs and biological under the direction of an authorized prescriber; and (2) Develop and implement policies and procedures for pharmacy services in accordance with accepted professional practice. B. Administration of Drugs. (1) Staff shall prepare and administer drugs according to established policies and acceptable standards of practice.

171. COMAR 10.34.19.08 Batch Preparation states: (A) A pharmacist may prepare batched sterile preparations for future use in limited quantities supported by prior valid prescriptions or physician orders before receiving a valid written prescription or medication order. (B) Batch preparation of specific compounded sterile preparations is acceptable if the: (1) Pharmacist can document a history of valid prescriptions or physician orders that have been generated solely within an established professional prescriber-patient-pharmacist relationship and (2) Pharmacy maintains the prescription on file for such preparations dispensed.

172. COMAR 10.34.19.06 (B) states: "The dispensed container for any compounded sterile preparation shall include labeling according to Maryland law and regulations, in addition to the following information that is required by federal law: ... (5) The name of the patient"

173. In order to purchase compounded drugs from NECC, it was necessary for both NECC and the Health Care Providers to comply with Massachusetts state law, which governed the compounding and dispensing activities of NECC according to Massachusetts law where and when, as here, a Massachusetts pharmacy is asked to fill and dispense a controlled substance prescribed by an out-of-state licensed prescriber.

174. Massachusetts law does not permit the practice of ordering and dispensing compounded drugs for office use, requiring instead an individual prescription for a specific named patient. Massachusetts General Law Chapter 94C and Department of Public Health regulations (Code of Massachusetts Regulations §721.000) require that pharmacies and pharmacists dispense medications pursuant to a valid prescription from an authorized practitioner for a specific patient. This prescription must be valid as defined under Massachusetts statutes and regulations, not under the rules governing prescriptions in the recipient state."[1] These laws

[1] The Commonwealth of Massachusetts Executive Office of Health and Human Services, Department of Public Health, Division of Health Professionals Licensure, Board of Registration in Pharmacy, *Advisory:*

provide that that writing prescriptions for the "general dispensing to patients"[2] is forbidden; that the name of a particular patient and prescribing doctor appear on the prescription;[3] and regulations require that the name and address of a particular patient be present on a prescription's label. Massachusetts prescription dispensing policy thereby maintains the traditional physician-pharmacist- patient relationship, thereby greatly increasing the likelihood that compounded drugs will be used in a timely and safe manner.

175. The Maryland Consumer Protection Act (hereinafter "CPA") establishes minimum standards of conduct in the marketplace to protect consumers. To establish a violation of the CPA, a Claimant must prove that the Defendant engaged in unfair and deceptive trade practices in connection with the sale or offer for sale of consumer goods, causing the Claimant to sustain injury. *Morris v. Osmose Wood Preserving*, 340 Md. 519, 538-539 (1995). The deceptive practice must occur in the sale or offer for sale to consumers. A private party suing under the CPA must establish actual injury or loss. *Id.* at 538.

176. The Massachusetts analog to Maryland's Consumer Fraud Act is Mass. Gen. Laws Ann. Ch. 93A et seq. (**"Chapter 93A"**) Chapter 93A also prohibits false representations deceptive acts and practices and makes violations of statutes, regulations and guidelines intended to protect consumers safety a *per se* violation of the Act, giving rise to a private cause of action for damages, multiple damages, fees and costs.

177. Maryland's CPA and Massachusetts' Chapter 93A are not mutually exclusive laws and both Acts constitutionally and textually may and should apply at the same time to the misconduct of a party herein because both State's laws prohibit and proscribe the misconduct

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Compounding Pharmacies and Pharmacists (October 2012), http://www.mass.gov/cohhs/docs/dph/quality/boards/pharmacy-alert-compounding.pdf.

[2] Mass. Gen. Laws Ann. ch. 94C, § 19.

[3] Mass. Gen. Laws Ann. ch. 94C, § 22.

and both State's under dual sovereignty principles have an independent right to apply its law and provide remedy where applicable.

178. Maryland Courts and Judicial Proceedings §5-405 Sealed container defense in product liability. … (b) Elements of defense to action against product's seller. – It shall be a defense to an action against a seller of a product for …personal injury allegedly caused by defective design or manufacture of a product if the seller establishes that: …The seller in the performance of the duties he performed or while the product was in his possession could not have discovered the defect while exercising reasonable care; … (c) *Defense not available.* – The defense provided in subsection (b) of this section is not available if: (1) The manufacturer is not subject to service of process under the laws of this State or the Maryland Rules".

V. SUBSTANTIVE COUNTS

A. SUBSTANTIVE COUNTS AGAINST HEALTH CARE PROVIDERS

COUNT I: SURVIVAL ACTION AGAINST HEALTH CARE PROVIDER DEFENDANTS – MEDICAL MALPRACTICE –NEGLIGENCE

179. Plaintiff Meghan Handy, as Personal Representative of the Estate of Brenda Lee Rozek, hereby sues the Defendants and for this cause of action states:

180. Plaintiff Meghan Handy repeats herein all the above as if the same were repeated verbatim.

181. At all times relevant herein, Decedent's physician, Ritu T. Bhambhani, M.D., was a practicing pain medicine specialist and the medical director of Box Hill Surgery Center. It is alleged that Box Hill Surgery Center and Medical Director Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC. were acting as principals/agents and/or vice versa of each other at all times relevant herein and had a relationship of principal/agent. It is alleged that this relationship

existed in 2012 at the time Decedent's cervical steroid injection was administered by Dr. Bhambhani at Box Hill Surgery Center.

182. The Defendants had a duty to exercise reasonable care to ensure that the drugs they purchased in order to sell and administer to their patients, including Decedent, were purchased from drug companies that complied with the laws regarding pharmaceuticals.

183. The Defendants had a duty to exercise reasonable care to ensure that the drugs they provided to their patients, including Decedent, were purchased from a company that made safe and effective drugs.

184. The Defendants had a duty to exercise reasonable care to ensure that the drugs they provided to their patients, including Decedent, were purchased from a company that utilized proper quality control, safety, and sterility measures in order to minimize the possibility that the drugs would become adulterated or contaminated.

185. The Defendants had a duty to exercise reasonable care to avoid administering contaminated drugs, or drugs they knew or should have known to be contaminated, to Decedent.

186. The Defendants had a duty to provide Decedent with reasonable care and treatment.

187. The Defendants as part of their duties as Decedent's learned intermediary had a duty to obtain informed consent from Decedent for the procedure performed on Decedent, in the course of which adequately and accurately describing to Decedent the nature of the procedure, as well as the risks of such procedure, including pertinent information regarding the drugs that were to be administered during such procedure.

188. In this case, where the drug came from an unaccredited, mass producing, out-of-state compounding pharmacy that was neither inspected nor regulated by the FDA, the

Defendants had a duty to inform Decedent of the nature and source of the drug and the dangers associated therewith.

189. The Defendants, by and through their actual and/or apparent agents, servants, and/or employees breached the above-described duties of care, thereby deviating from the applicable standards of care, and were otherwise negligent, careless, and reckless in that among other things:

a. the Defendants failed to exercise reasonable and prudent care to ensure that the drugs they purchased and provided at charge to Decedent were made by NECC in compliance with all applicable pharmaceutical laws;

b. the Defendants failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided at charge to Decedent were acquired from a reputable and able source and supply in compliance with all applicable pharmaceutical laws;

c. the Defendants failed to know and understand the source and supply of the drug they provided to Decedent;

d. the Defendants failed to use appropriate, necessary and reasonable due diligence and investigatory steps and measures necessary to vet, evaluate and determine the safety and quality of NECC's drugs, and in particular, determine if NECC could properly and suitably compound, package and provide sterile preservative-free drugs for administration to Decedent;

e. the Defendants failed to follow the reasonable ASHP *Guidelines on Outsourcing Sterile Compounding Services*, which had they followed, would have established that NECC's products were unsafe or unsuitable for administration to the Decedent;

f. the Defendants failed to exercise reasonable and prudent care to ensure that the drug they provided to Decedent was produced in sanitary, sterile conditions;

g. the Defendants failed to properly inform Decedent that drug was compounded and was not manufactured at a facility approved by the FDA;

h. the Defendants failed to properly inform Decedent of the risks and dangers associated with the administration of the drug; and they failed to inform her that they had obtained the drug via mail order from NECC, a mass-producing, unaccredited, non-FDA regulated compounding pharmacy;

i. the Defendants failed to exercise reasonable care to avoid administering to Decedent an adulterated, contaminated and unreasonably dangerous drug;

j. the Defendants failed to conduct adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

k. the Defendants failed to visit NECC's facilities before procuring compounded drugs from NECC;

l. the Defendants failed to investigate and exercise sufficient due diligence before administering drugs procured from NECC, including failing to investigate or inquire concerning NECC's compounding practices, standard operating procedures, pharmacist training, and risk management protocols;

m. the Defendants failed to determine whether NECC had a history of recalling compounded medications before procuring medicines from that company;

n. the Defendants failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring drugs from NECC;

o. the Defendants failed to determine whether NECC had a history of product liability suits before procuring medicines from that company;

p. the Defendants failed to determine whether NECC was accredited by any legitimate accreditation organization suits before procuring medicines from that company;

q. the Defendants failed to keep abreast of the dangers of sterile compounding;

r. the Defendants purchased compounded drugs in bulk from NECC without using patient specific individual prescriptions in contravention of law;

s. It is believed the Defendants failed to appropriately store drugs purchased from NECC to reduce the risk of the growth of contaminants;

t. the Defendants failed to adequately supervise and train the physicians, nurses, agents and employees who ordered drugs from NECC;

u. the Defendants failed to implement policies and procedures that would prevent the procurement of purportedly sterile drugs from an out-of-state compounding pharmacy with a deplorable facility and sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;

v. the Defendants administered drugs to Decedent without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;

w. the Defendants failed to promptly notify Decedent that she was injected with potentially contaminated steroids and failed to recommend that he receive prompt treatment of his potential infections and other symptoms;

x. the Defendants selected and administered a preservative free version of MPS steroid medication where and when versions with preservatives were available and or there were manufactured preservative free therapeutic substitutes available;

y. the Defendants dispensed a medication not prescribed and dispensed by the compounding pharmacy for Decedent, but rather a compounded medication prescribed and dispensed by NECC for anther purported patient; and

z. the Defendants failed to exercise reasonable care in such other manners as may be shown through discovery and at trial.

190. The physicians, nurses, agents, employees and representatives who decided to procure drugs from NECC and who administered them to the Decedent were employees or agents of the Defendants, and they were acting within the course and scope of their employment or agency. Accordingly, the Defendants are liable for the consequences of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.

191. As a direct and proximate result of the negligence of Defendants, Decedent was administered a contaminated steroid injection which led to a painful and unnecessary death. She endured conscious pain and suffering, endured numerous invasive procedures, incurred significant medical expenses and bills, and was otherwise physically and emotionally injured and damaged. In addition, the Estate was caused to incur medical and funeral expenses as a direct and proximate result of the negligence of the Defendants.

192. The actions of the Defendants did not meet even the most minimal diligence to ensure that they were not injecting contaminated, adulterated, tainted, and unreasonably dangerous drugs directly into the bodies of their patients, including Decedent.

193. The acts and omissions of the Defendants constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including Decedent.

194. It is alleged that all of the Decedent's injuries and damages occurred as a direct and proximate cause of the negligence of the Defendants as described hereinabove, without any negligence on the part of the Decedent contributing thereto.

195. At all times material hereto, Defendants purchased, stored, handled, sold, used, administered, and/overall possessed and utilized contaminated MPA with willful and intentional disregard to the individual rights of Decedent, warranting an award of punitive damages to Decedent.

196. The Defendants represented that Decedent received FDA-approved Depo Medrol when in fact they injected Decedent with NECC's compounded MPA.

197. Defendants thereby acted with oppression, fraud and malice toward Decedent, therefore, Plaintiff requests additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in amounts sufficiently large to be an example to others, and to deter these Defendants and others from engaging in similar conduct in the future.

198. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiffs therefore are entitled to an award of punitive damages against the Defendants.

WHEREFORE, Plaintiff Meghan Handy, as Personal Representative of the Estate of Brenda Lee Rozek, prays for relief as follows:

(a) Compensatory damages in an amount in excess of $30,000.00;

(b) Punitive damages under the laws of Maryland, Massachusetts and/or other applicable law;

(c) All costs and attorneys' fees recoverable by law; and

(d) Such other and further relief as the Court deems appropriate.

COUNT II: SURVIVAL ACTION AGAINST DEFENDANTS – INFORMED CONSENT

199. Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, hereby sues the Defendants and for this cause of action states:

200. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

201. It is alleged that the Decedent was not afforded appropriate informed consent with respect to the risk of the procedure.

202. The Defendants provided high risk and unreasonably dangerous contaminated NECC compounded drugs to patients, including Decedent, in the place of safe, medically acceptable drugs.

203. The Defendants failed to inform their patients at Box Hill Surgery Center, including Decedent, that they were being administered an unsafe, unreasonably dangerous drug compounded by NECC rather than a high quality drug produced by an FDA regulated manufacturer.

204. The Defendants represented Decedent was receiving FDA-approved DepoMedrol when in fact they injected Decedent with NECC's compounded preservative free MPA.

205. Many, if not all, of the Defendants prepared a Consent for Treatment form. The form, which was presented to Decedent by the Defendants, and which Decedent read and relied upon when agreeing to accept treatment, failed to inform the Decedent of the risks and benefits

of the procedures before it was performed. When presenting the form to Decedent, the Defendants knew that nobody on its behalf would be informing Decedent of the inferior, far more risky and unreasonably dangerous nature of the compounded NECC drug that would be administered to Decedent. Defendants knew that if Decedent was informed of the true nature and source of the compounded NECC drugs, Decedent would decline treatment with NECC compounded drugs, threatening the Defendants' profits.

206. As a proximate result of the Defendants' wrongful conduct, Decedent underwent the procedure which used NECC's contaminated preservative free MPA, when she reasonably would not have, and suffered grievous bodily injury, required extensive medical treatment, incurred substantial medical bills, suffered severe mental anguish, and died a horrendous death.

WHEREFORE, Plaintiff, Meghan Handy, as Personal Representative of the Estate of Brenda Lee Rozek, prays for relief as follows:

(a) Compensatory damages in an amount in excess of $30,000.00;

(b) All costs and attorneys' fees recoverable by law; and

(c) Such other and further relief as the Court deems appropriate.

COUNT III: SURVIVAL ACTION AGAINST DEFENDANTS – BATTERY

207. Plaintiff Meghan Handy, as Personal Representative of the Estate of Brenda Lee Rozek, hereby sues the Defendants and for this cause of action states:

208. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

209. As part of the medical treatment Decedent received at the Defendants' facility, their agents and/or employees purchased, prescribed and administered, via injection into Decedent's body, NECC drugs which were not sterile and which contained substances, including fungal or bacterial contamination, harmful to human life. Decedent, however, was unaware of

the substantial health and safety risk inherent in the use of NECC drugs, that the drugs contained harmful fungus and other adulterants and did not consent to the injection of contaminated drugs into her body.

210. As a direct and proximate result of Defendants wrongful acts set forth herein, Decedent was injected by Defendants with NECC contaminated drugs, intentionally inflicting and causing a harmful and offensive contact with Decedent's body.

211. As a direct and proximate result of this unwanted offensive and harmful contact, Decedent suffered grievous bodily injury, required extensive medical treatment, incurred substantial medical bills, suffered severe mental anguish, and died a horrendous death.

WHEREFORE, Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, prays for relief as follows:

(a) Compensatory damages in an amount in excess of $30,000.00;

(b) All costs and attorneys' fees recoverable by law; and

(c) Such other and further relief as the Court deems appropriate.

B. SUBSTANTIVE COUNTS AGAINST THE NECC RELATED DEFENDANTS, ARL, LIBERTY and UNIFIRST

COUNT IV: SURVIVAL ACTION AGAINST NECC RELATED DEFENDANTS NEGLIGENCE UNDER MASSACHUSETTS OR OTHER APPLICABLE STATE LAW

212. Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, hereby sues the NECC Related Defendants and for this cause of action states:

213. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

214. As a designer, tester, compounder, seller, marketer, supplier, and/or distributor of consumer products, the ARL and NECC Related Defendants, Ameridose, ARL, GDC,

MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin, owed a duty to the Decedent to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to the Decedent.

215. Specifically, but without limitation:

a. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Decedent and her physicians a duty to compound, and provide methylprednisolone acetate that was safe and free of contamination.

b. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Decedent and her physicians a duty to provide reasonable and correct warnings, instructions and labeling to Plaintiff or her physicians.

c. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Decedent and her physicians a duty to properly store and ship methylprednisolone acetate.

d. ARL owed Decedent duties to properly conduct tests to insure that the NECC methylprednisolone acetate was sterile, safe and free of contamination, and to not authorize and prevent its reports from being used in the marketing of products that were not fully tested where and when it knew or had reason to know that was occurring.

216. The NECC-Related Defendants breached these respective duties and were otherwise negligent in their design, compounding, formulation, making, creation, sale, testing,

marketing and distribution of the recalled MPA steroid medication, which was administered to Decedent. These Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, formulator, maker, creator, tester, seller, marketer and distributor of sterile preparations and medications, as licensed to do so by the Commonwealth of Massachusetts.

217. The NECC-Related Defendants, by and through their supervisors, staff and agents engaged in designing, compounding, formulation, making, creation, sales, testing, marketing and distributing the recalled MPA in a negligent manner.

218. The NECC-Related Defendants further breached their respective duties of care by failing to store, hold and compound the components of the recalled medications; by failing to properly design, compound, formulate, create, make, test, sell and/or distribute MPA so that it would not be contaminated with a fungus; by failing to properly maintain facilities where sterile medications were compounded, packaged or stored in a clean, sanitary manner, or taking reasonable steps and measures to assure these functions were performed in clean, sanitary and sterile facilities; by failing to oversee the security and quality control of NECC's or their compounding and distribution facilities; and/or by allowing contaminated and unsafe medications compounded to reach the stream of commerce for use by Decedent and her physicians.

219. Amcridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin breached the duties owed to Decedent by failing to use reasonable care in designing, compounding, formulating, making, creating, testing, marketing, distributing and/or selling preservative free MPA.

220. NECC has been declared insolvent by the Bankruptcy Court presiding over its Bankruptcy Petition and prosecution of any and all actions against it are stayed.

221. In addition to violating the laws of Massachusetts where NECC was headquartered and maintained its facility for compounding, packaging, storing and distributing contaminated and adulterated drugs which were then shipped and distributed to Maryland for administration to patients, including Decedent, all or some of the NECC-Related Defendants also violated the Maryland Consumer Protection Act.

222. The negligence of Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin was a proximate cause of Decedent's injuries, harm and losses and eventual premature death.

223. As a direct and proximate cause of ARL and the NECC Related Defendants' joint and several acts of negligence, carelessness and recklessness, Decedent was exposed to fungal contaminated steroid medication on August 31, 2012.

224. As a direct and proximate result of negligence of Defendants identified in this Count, Decedent was injected with a contaminated dose of methylprednisolone acetate and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

WHEREFORE, Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, prays for relief as follows:

(a) Compensatory damages in an amount in excess of $75,000.00;

(b) Punitive damages under the laws of Massachusetts and/or other applicable law.

(c) All costs and attorneys' fees recoverable by law; and

(d) Such other and further relief as the Court deems appropriate.

COUNT V: SURVIVAL ACTION AGAINST NECC RELATED DEFENDANTS NEGLIGENCE UNDER MASSACHUSETTS OR OTHER APPLICABLE STATE LAW -STRICT LIABILITY – MANUFACTURING DEFECT

225. Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, hereby sues the NECC Related Defendants and for this cause of action states:

226. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

227. NECC's preservative free MPA was defectively manufactured and unreasonably dangerous when it left the possession of the NECC Related Defendants in that it was contaminated with toxic microbes, including fungus, creating a unreasonably dangerous and potentially deadly product.

228. Plaintiffs' Decedent, without knowledge of the defective and dangerous characteristics of the MPA, was injected with tainted MPA for its intended purpose, and in a manner reasonably anticipated.

229. Plaintiffs' Decedent was an ordinary user of the product sold, distributed, supplied, manufactured, designed, developed, marketed and/or promoted by Defendant and, therefore, it was foreseeable that Plaintiffs' Decedent would use the product as indicated herein.

230. As a direct and proximate result of the NECC MPA preservative free manufacturing defect, Plaintiffs' Decedent has been caused to sustain serious, painful, and fatal injuries including, but not limited to fungal meningitis, resulting in great physical and mental pain and suffering until she died, among other damages.

231. Had the NECC MPA preservative free medication been properly, adequately and appropriately compounded and dispensed, Plaintiff's Decedent would not have suffered the above-identified injuries and damages.

WHEREFORE, Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, prays for relief as follows:

(a) Compensatory damages in an amount in excess of $75,000.00;

(b) Punitive damages under the laws of Maryland, Massachusetts and/or other applicable law;

(c) All costs and attorneys' fees recoverable by law; and

(d) Such other and further relief as the Court deems appropriate.

COUNT VI: SURVIVAL ACTION AGAINST NECC RELATED DEFENDANTS — BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

232. Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, hereby sues the NECC Related Defendants and for this cause of action states:

233. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

234. The NECC MPA preservative free medication was defective when it left the possession and control of the NECC Related Defendants in that it contained toxic microbes, including fungus.

235. Plaintiff's Decedent was an ordinary user of the product sold, distributed, supplied, manufactured, designed, developed, marketed and/or promoted by the NECC Related Defendants and, therefore, it was foreseeable that Plaintiffs' Decedent would use the product as indicated.

236. The NECC MPA preservative free medication was unfit for its ordinary purpose and as a direct and proximate result Plaintiffs' Decedent, was caused to sustain serious, painful, and eventually fatal injuries as described herein.

WHEREFORE, Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, prays for relief as follows:

(a) Compensatory damages in an amount in excess of $75,000.00;

(b) All costs and attorneys' fees recoverable by law; and

(c) Such other and further relief as the Court deems appropriate.

COUNT VII: SURVIVAL ACTION AGAINST NECC RELATED DEFENDANTS - NEGLIGENCE *PER SE*

237. Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, hereby sues the NECC Related Defendants and for this cause of action states:

238. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

239. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Decedent a duty under Massachusetts law to maintain the premises of the NECC pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

240. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin breached the duties owed to Decedent by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

241. As a direct and proximate cause of the Defendants Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin's negligence, carelessness and recklessness in violating these statutory imposed duties, Decedent was exposed to fungal contaminated steroid medication on August 31, 2012.

242. As a direct and proximate result of negligence of the defendants identified in this Count, Decedent was injected with a contaminated dose of methylprednisolone acetate and

consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

WHEREFORE, Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, prays for relief as follows:

(a) Compensatory damages in an amount in excess of $75,000.00;

(b) Punitive damages under the laws of Massachusetts and/or other applicable law;

(c) All costs and attorneys' fees recoverable by law; and

(d) Such other and further relief as the Court deems appropriate.

COUNT VIII: SURVIVAL ACTION AGAINST NECC RELATED DEFENDANTS AND ARL- NEGLIGENT SUPERVISION NEGLIGENCE PER SE

243. Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, hereby sues the NECC Related Defendants and ARL and for this cause of action states:

244. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

245. ARL, and the NECC Related Defendants each respectively had an obligation and duty to exercise due care, and comply with the then existing standard of care to investigate and hire professional and competent employees to create, test, package, market and/or distribute the compounded medications and to make sure the compounded drugs being made, tested, packaged and stored did not create any harm or risk to Decedent and others who received the compounded medications.

246. Defendants Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin each also respectively had an obligation and duty to exercise due care and comply with the then existing standard of care to investigate and hire professional and competent employees or vendors to maintain NECC's production, packaging and storage facility and make sure the purported compounded

sterile drugs did not create any harm or risk to Decedent and others who received NECC's compounded medications.

247. In breach of these duties, ARL and the NECC Related Defendants failed to exercise due care and failed to supervise their respective employee(s), agent(s) or vendor(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

a. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly test the steroid medication and these Defendants were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding this important task and function;

b. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly compound, sterilize, package, label, store and dispense the steroid medication and these Defendants were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding these important tasks and functions; and/or

c. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly review prescriptions for NECC's compounded medications for compliance with applicable prescription laws and/or gave incorrect information or instructions on requisite prescription requirements, and these Defendants were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding these important tasks and functions.

d. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly instruct, warn or advise as to the storage, handling and pre-administration

administration inspection of NECC's preservative free sterile compounded and/or gave incorrect information or instructions or warnings, and these Defendants were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding these important tasks and functions

e. These Defendants were otherwise negligent in hiring, training, and supervising their employees, agents or vendors relevant to this matter.

248. ARL and the NECC-Related Defendants knew, or should have known, that their respective employee or agent did not follow proper procedures and precautions and knew or should have known of the risks created by failing to do so.

249. As a direct and proximate cause of these breaches of duty ARL's and the NECC-Related Defendants permitted the subject MPA steroid lots to become contaminated and distributed to patients throughout the United States, including Decedent.

250. As a direct and proximate cause of ARL's and the NECC Related respective negligence, carelessness and recklessness, Decedent was exposed to fungal contaminated steroid medication on August 31, 2012.

251. As a direct and proximate result of negligence of the Defendants identified in this Count, Decedent was injected with a contaminated dose of methylprednisolone acetate and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

WHEREFORE, Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, prays for relief as follows:

(a) Compensatory damages in an amount in excess of $75,000.00;

(b) Punitive damages under the laws of Maryland, Massachusetts and/or other applicable law;

(c) All costs and attorneys' fees recoverable by law; and

(d) Such other and further relief as the Court deems appropriate.

COUNT IX: SURVIVAL ACTION AGAINST LIBERTY– NEGLIGENCE AND GROSS NEGLIGENCE

252. Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, hereby sues Defendant Liberty and for this cause of action states:

253. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

254. Liberty owed Decedent a duty to exercise reasonable care and to follow all applicable laws and standards during the manufacture, construction, installation, design, certification, and ongoing maintenance of the Cleanrooms in order to prevent or eliminate contamination of the Cleanrooms.

255. Liberty failed to exercise reasonable care in one or more of the following ways, so far as is presently known:

a. by failing to properly design and install the 2006 and 2008 Cleanroom ceiling grids, ceiling panels, light fixtures, and HEPA filtration modules;

b. by failing to properly design and install the 2006 and 2008 Cleanroom fire suppression system;

c. by failing to use proper materials in the construction of the ceiling of the Cleanrooms;

d. by failing to properly survey existing Cleanrooms and the facility as a whole to properly assess the risks associated with construction of subsequent Cleanrooms;

c. by failing to install a hard cap/hard ceiling over the ceiling of each Cleanroom to protect from contamination, despite Liberty's actual and/or constructive knowledge that the areas between the ceilings of the 2006 and 2008 Cleanrooms were prone to excessive contamination and water damage;

f. by prematurely certifying the 2006 and 2008 Cleanrooms;

g. by disrupting or otherwise breaching the cleanliness of the Cleanrooms through the installation of faulty ceiling grids, improper materials, and the conduct of subsequent work to each Cleanroom, resulting in or contributing to their contamination;

h. by failing to take reasonable steps to properly certify the Cleanrooms to ensure their cleanliness as required for their anticipated use;

i. by committing other violations as shall be revealed in discovery.

256. Decedent was a foreseeable victim of Liberty's negligence. Liberty knew that NECC and Ameridose were compounding drugs at their Massachusetts' facility for national distribution and for use in patients such as Decedent.

257. Liberty's wrongful conduct and negligence resulted in Decedent's suffering physical injuries and economic losses.

258. Liberty's conduct set out above constitutes gross negligence and a reckless disregard for human life and safety, thus warranting the imposition of punitive damages.

WHEREFORE, Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, prays for relief as follows:

(a) Compensatory damages in an amount in excess of $75,000.00;

(b) Punitive damages under the laws of Maryland Massachusetts and/or other applicable law;

(c) All costs and attorneys' fees recoverable by law; and

(d) Such other and further relief as the Court deems appropriate.

COUNT X: SURVIVAL ACTION AGAINST UNIFIRST– NEGLIGENCE AND GROSS NEGLIGENCE

259. Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, hereby sues Defendant Unifirst and for this cause of action states:

260. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

261. UniFirst owed Decedent duty to exercise reasonable care to follow all applicable laws and standards, as well as NECC standard procedures, during the ongoing and regular maintenance and cleaning of the Cleanrooms in order to prevent or eliminate contamination of the Cleanrooms.

262. UniFirst knew or should have known that products produced, sold, and shipped by NECC required a sterile environment, and that such products would be used by end consumers such as Decedent. UniFirst knew that end consumers of NECC products were the intended beneficiaries of the services to be rendered by UniFirst to NECC. UniFirst's knew that customers of a business like NECC expect and rely upon a clean and a safe environment for the production of goods. UniFirst knew this for nearly four years before the recall of the NECC Contaminated Drugs.

263. UniFirst failed to exercise reasonable care in one or more of the following ways, so far as is presently known:

a) UniFirst employees, contractors and/or representatives, including those within the UniClean division, entered the Cleanrooms (including the anterooms) in street

clothes, without donning sterile or contaminant-free clothing such as shoe covers, hair caps, coveralls, and gloves that were readily available at the NECC facilities, thereby failing to follow its own standards and policies;

b) UniFirst employees, contractors and/or representatives brought into the NECC anterooms and Cleanrooms cleaning equipment, including mops, mop heads, spongers, and buckets that had been moved through exterior environments, even though such equipment had not been sanitized or cleaned appropriately, allowing contamination to occur throughout various parts of the NECC facility, such actions failing to meet UniFirst's own standards as well as recognized industry standards;

c) UniFirst employees, contractors and/or representatives failed to clean or wipe footwear on mats used in the cleanroom entry process, thereby allowing contaminants into and throughout the Cleanrooms; and

d) UniFirst employees, agents, contractors and/or representatives were negligently supervised, and failed to adhere to and follow NECC standard operating procedures.

263. Plaintiff was a foreseeable victim of UniFirst's negligence. UniFirst knew that the NECC-Related Parties were compounding drugs at their facility for national distribution and for use in patients such as Decedent.

264. The wrongful conduct and negligence of UniFirst resulted in Plaintiff's suffering serious physical injuries, distress and eventual death.

265. As a direct and proximate result of UniFirst's negligence, as well as that of UniFirst's employees, agents, independent contractors, businesses, or others associated with

and/or providing services, Decedent is entitled to recover all allowable elements of damage from UniFirst for her injuries and losses.

266. UniFirst's conduct set out above constitutes gross negligence and a reckless disregard for human life and safety, thus warranting the imposition of punitive damages.

WHEREFORE, Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, prays for relief as follows:

(a) Compensatory damages in an amount in excess of $75,000.00;

(b) Punitive damages under the laws of Massachusetts and/or other applicable law;

(c) All costs and attorneys' fees recoverable by law; and

(d) Such other and further relief as the Court deems appropriate.

C. SUBSTANTIVE COUNTS AGAINST NECC RELATED PARTIES, HEALTH CARE PROVIDERS and ARL

COUNT XI: SURVIVAL ACTION AGAINST NECC RELATED DEFENDANTS AND HEALTH CARE PROVIDERS – CIVIL CONSPIRACY AND CONCERTED ACTIVITY

267. Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, hereby sues the NECC Related Defendants and the Health Care Providers and for this cause of action states:

268. Plaintiffs incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

269. MPA is a controlled substances under the laws of Massachusetts, requiring a valid prescription under Massachusetts' pharmacy statutes and regulations.

270. Massachusetts' law governs dispensing of controlled substances by Massachusetts' pharmacies, even when shipped out of the state.

271. In connection with obtaining bulk or office supplies of preservative free MPA for administration to Box Hill Surgery Center's patients, including Plaintiffs' Decedent, the Health Care Providers conspired with NECC and the NECC related Defendants by agreeing to participate in a scheme to circumvent and violate Massachusetts' pharmacy statutes and regulations that were intended to protect patient safety, including Massachusetts' pharmacy laws and regulations prohibition on dispensing controlled substances pursuant to so called "office supply" prescriptions. The NECC Related Defendants and the Health Care Providers accomplished this unlawful purpose via the unlawful means of the Health Care Providers submitting to NECC bogus or past lists of purported individual patients on NECC's prescription orders forms by fax or mail in order to order and obtain by express mail compounded preservative free MPA for administration to patients at Box Hill Surgery Center's Maryland facility. The NECC Related parties in turn suggested and permitted this practice which was in direct violation of Massachusetts' pharmacy and controlled substances law, and, further, caused or facilitated the dispensing of NECC's compounded preservative free MPA to Box Hill Surgery Center as well as other health care faculties throughout the United States.

272. The NECC Related Defendants and the Health Care Provider's acts in furtherance of the conspiracy resulted in NECC being able to falsely appear in compliance with Massachusetts' pharmacy statutes and regulations when in fact it was not in compliance.

273. The Health Care Providers knew, or reasonably should have known, that patient specific names were required by NECC in order to dispense drugs it compounded by virtue of the fact that NECC's standard prescription order form for MPA and other drugs requested patient specific information. Instead of filling out these standard forms properly, the Health Care

Providers ordered NECC pharmaceuticals in bulk submitting a list of previous or bogus patient names.

274. Plaintiffs' Decedent was not properly and validly listed on any NECC prescription order form submitted by Box Hill Surgery Center to NECC.

275. The concerted action of NECC and Health Care Providers resulted in injury and the eventual death of Plaintiff's Decedent as described herein.

276. The NECC Related Defendants and the Health Care Providers are liable for the acts of their co-conspirators NECC, as well as each other.

WHEREFORE, Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, prays for relief as follows:

(a) Compensatory damages in an amount in excess of $30,000.00 for malpractice claims against the Defendants and in excess of $75,000 on all other claims;

(b) Punitive damages under the laws of Maryland, Massachusetts and/or other applicable law;

(c) All costs and attorneys' fees recoverable by law; and

(d) Such other and further relief as the Court deems appropriate.

COUNT XII: SURVIVAL ACTION AGAINST NECC RELATED DEFENDANTS ARL, AND HEALTH CARE PROVIDERS – VIOLATION OF MASSACHUSETTS AND MARYLAND STATE CONSUMER PROTECTION STATUTES

277. Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, hereby sues the NECC Related Defendants, ARL and the Health Care Providers and for this cause of action states:

278. Plaintiffs incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

279. The NECC Related Defendants and Health Care Providers engaged in trade and commerce within the State of Maryland and the Commonwealth of Massachusetts.

280. The NECC Related Defendants and Health Care Providers have a statutory duty to refrain from unfair or deceptive acts or trade practices in the promotion and sale of the NECC contaminated drugs.

281. As described herein, the Health Care Providers' submitted to NECC bogus or past patient named in order to obtain office supplies of preservative free MPA drugs from NECC in violation of Massachusetts' controlled substances and pharmacy laws and regulations. Such submissions constitute actionable violations of Maryland's and Massachusetts' respective consumer protection statutes.

282. As described herein, the NECC Related Defendants and Health Care Providers represented that the medication being administered had characteristics, uses and benefits that they did not have.

283. As describe herein, the NECC Related Defendants and Health Care Providers represented that their products were of a particular standard, origin, manufacturer, quality and grade that they either knew or should have known was not of the standard, origin, manufacturer, quality or grade described.

284. The NECC-Related Defendants and Health Care Providers failed to provide accurate disclosures of all material information before Decedent agreed to be injected with an NECC contaminated drug.

285. The Health Care Providers represented to their patients and their medical benefits providers that they were being administered or had been administered FDA-approved

DepoMedrol when in fact they injected patients, including Decedent, with NECC's compounded MPA.

286. The NECC-Related Defendants and Health Care Providers willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, constituting a violation of the consumer protection statutes set forth herein.

287. The conduct and omission of the Health Care Providers, NECC, Ameridose's, MSM/MSMSW's, Gregory Conigliaro's, Douglas Conigliaro's, Carla Conigliaro's, Barry Cadden's, Lisa Cadden's, Glenn Chin's and/or ARLs', constituted unfair and deceptive acts and practices under Maryland and Massachusetts unfair and deceptive acts and practices laws, including, but not limited to all or some of the following:

a. Misrepresenting the nature, quality, and characteristics about NECC's compounded MPA;

b. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety and the dispensing of pharmaceutical products;

c. Unfairly exposing unknowing consumers, including Decedent, to significant, unnecessary risk of harm and actual harm and injury; and

d. All other unfair, fraudulent and deceptive acts set forth herein

288. The NECC Related Parties and Health Care Providers acts and omission alleged herein aided and abetted the wrongful and tortious conduct and activities of each, and/or served to further the conspiracy alleged herein that the NECC Related Parties, ARL and the Health Care Providers were parties to, while at the same time, and under false pretenses, allowed the Health Care Providers to obtain money from Decedent and/or their medical care benefit providers for

NECC's contaminated drugs that would not have been paid had the Health Care Providers not engaged in unfair and deceptive conduct.

289. Had the NECC Related Parties, ARL and the Health Care Providers not engaged in the deceptive conduct described above, Decedent would not have purchased and/or paid for NECC's contaminated MPA.

290. The Health Care Providers' acts omissions, and civil conspiracy alleged herein constitute unfair competition, unfair or deceptive acts or practices, and/or false representations in violation of Maryland's and Massachusetts' respective consumer protection statutes, which statutes are not mutually exclusive and under the doctrine of Dual Sovereignty may each apply.

291. The Health Care Providers' willful and knowing withholding of important safety information and critical product information constitutes a violation of Maryland's and Massachusetts' consumer protection statutes set forth herein.

292. The NECC Related Parties, ARL and the Health Care Providers actively, knowingly, and deceptively concealed the MPA product's dangerous properties and life-threatening risks of which they knew or should have known. This conduct evidences bad faith and unfair and deceptive practices.

293. The NECC Related Parties, ARL and the Health Care Providers engaged in conduct as described herein that created a likelihood of confusion and misunderstanding.

294. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally the Health Care Providers were unethical and unscrupulous, and caused substantial injury to consumers. The Health Care Providers engaged in unconscionable actions and courses of action.

295. The NECC Related Parties', ARL's and the Health Care Providers' willfully engaged in the conduct described herein, which they knew was deceptive, in the course of business, trade and commerce, and had a deleterious impact on the public interest.

296. The NECC Related Parties, ARL and the Health Care Providers are liable to Plaintiffs for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

297. Decedent was injected with NECC Contaminated Drugs for personal use and thereby suffered ascertainable losses as a result of the Health Care Providers' actions in violation of the consumer protection laws.

298. The NECC Related Parties', ARL's and the Health Care Provider's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of the following state consumer protection statutes, as listed below.

- Md. Code Ann., Com. Law §§ 13-101 et seq; and
- Mass. Gen. Laws Ann. Ch. 93A et seq.

299. The NECC Related Parties, ARL and the Health Care Providers violated the statutes that were enacted in Maryland and Massachusetts to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the NECC MPA drug was fit to be used for the purpose for which it was intended, when, in fact, it was defective and dangerous, and by other acts alleged herein.

300. The actions and omissions of the NECC Related Parties, ARL and the Health Care Providers alleged herein are uncured or incurable deceptive acts under the statutes enacted

in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

301. Decedent relied upon the NECC Related Parties', ARL's and the Health Care Providers' misrepresentations and omissions in determining which product to be administered to her.

302. By reason of the unlawful acts engaged in by the NECC Related Parties, ARL and the Health Care Providers, and as a direct and proximate result thereof, Decedent has suffered ascertainable losses and damages.

303. As a direct and proximate result of the NECC Related Parties', ARL's and the Health Care Providers' violations of the states' consumer protection laws, Decedent sustained an ascertainable loss and other damages and are entitled to statutory and compensatory, damages in an amount to be proven at trial.

304. Pre-suit notice of this claim is not required. The NECC Related Parties in the NECC MDL proceedings, *In Re New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL No. 2419 , Dkt. No. 1:13-md-2419 (FDS) (D. Mass)), have agreed to waive pre-suit notice requirements, including MGL c. 93A's pre-suit demand requirement. The waiver is documented in Case Management Order No. 6 entered in MDL No. 2419 on June 28, 2013. ARL, and the Health Care Provides do not maintain a place of business or keep assets within the Commonwealth of Massachusetts thus negating the pre-suit notice requirement under Chapter 93A.

WHEREFORE, Plaintiff Meghan Handy as Personal Representative of the Estate of Brenda Lee Rozek, prays for relief as follows:

(a) Compensatory damages in an amount in excess of $30,000.00 for malpractice claims against the Defendants and in excess of $75,000 on all other claims, or as provided by applicable statue;

(b) Enhanced or statutory damages as provided under the laws of Maryland, Massachusetts and/or other applicable law.

(c) All costs and attorneys' fees recoverable by law; and

(d) Such other and further relief as the Court deems appropriate

D. WRONGFUL DEATH AND CONSORTIUM LOSS SUBSTANTIVE COUNT AGAINST ALL DEFENDANTS

COUNT XIII: WRONGFUL DEATH AND CONSORTIUM LOSS CLAIMS

305. Plaintiffs, Neil E. Rozek, Meghan Handy, Kristen Lowery, Frank D. Ragan, Sr. and JoAnne Ragan, bring these claims against all Defendants and repeat herein all the above as if the same were repeated verbatim.

306. Spouse Plaintiff, Neil E. Rozek, and Decedent, Brenda L. Rozek, were at all material times married to each other and were husband and wife at the time of the occurrence referred to in this matter. They had two daughters, Meghan Handy and Kristen Lowery, both whom are of adult age.

307. Decedent at the time of her death was also survived by her parents, Plaintiffs Frank D. Ragan, Sr. and JoAnne Ragan.

308. The Defendants negligence and other tortious conduct alleged above caused Spouse Plaintiff, Neil E. Rozek, to lose his wife, Brenda Rozek, resulting in his suffering pecuniary loss, mental anguish, emotional pain, loss of society, loss of companionship, loss of comfort, loss of protection, loss of marital care, loss of filial care, loss of attention, loss of guidance, and loss of advice and counsel.

309. Plaintiff, Neil E. Rozek, claims all allowable damages for Wrongful Death under Maryland law. He also claims loss of income and support from his late wife as a result of her

310. As a further proximate result of the Defendants' negligence and other tortious conduct alleged above, Plaintiffs, Neil E. Rozek, Meghan Handy, Kristen Lowery, Frank D. Ragan, Sr. and JoAnne Ragan, each has suffered mental anguish, emotional pain and suffering, loss of society, loss of companionship, loss of comfort, loss of attention, loss of advice, loss of counsel, and loss of guidance and claims all allowable damages under Maryland's wrongful death law for the loss of Brenda L. Rozek, deceased.

WHEREFORE, Plaintiffs pray for relief as follows:

(a) Compensatory damages in an amount in excess of $30,000.00 for malpractice claims against the Defendants and in excess of $75,000 on all other claims;

(b) Punitive damages under the laws of Maryland, Massachusetts and/or other applicable law;

(c) All costs and attorneys' fees recoverable by law; and

(d) Such other and further relief as the Court deems appropriate.

ROBERT J. WELTCHEK
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DEMAND FOR JURY TRIAL

Plaintiffs elect to have their case tried before a jury.

ROBERT J. WELTCHEK

MEGHAN HANDY, *et al.*	*	BEFORE THE
	*	
Claimants	*	HEALTH CARE
	*	
v.	*	ALTERNATIVE DISPUTE
	*	
BOX HILL SURGERY CENTER, LLC, *et al.*	*	RESOLUTION OFFICE
	*	
Health Care Providers	*	HCA No.: 2014-394
	*	

* *

ORDER OF TRANSFER

The Claimants, by and through counsel, having elected a Waiver of Arbitration under the provisions of Annotated Code of Maryland, Courts and Judicial Proceedings, Article, § 3-2A-06B, it is this 18th day of August, 2014, by the Health Care Alternative Dispute Resolution Office,

ORDERED, that this case shall be and is hereby, transferred to the United States District Court, or to the Circuit Court of the appropriate venue.

HARRY L. CHASE, DIRECTOR
Health Care Alternative Dispute Resolution Office

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that copies of the above ORDER OF TRANSFER have been mailed, postage prepaid, to all counsel.

HARRY L. CHASE, DIRECTOR